



FDA Facts: Gluten-Free Labeling

In August 2013, FDA issued a final rule to define the term “gluten-free” for voluntary use in the labeling of foods. Establishing a definition of the term “gluten-free” and uniform conditions for its use in food labeling will help ensure that American consumers with celiac disease are provided truthful and accurate information with respect to foods labeled gluten-free.

All foods labeled gluten-free on or after August 5, 2014 must meet all requirements of the gluten-free labeling final rule.

How is “gluten-free” defined in the rule?

“Gluten-free” is defined as a food that is either inherently gluten free; or does not contain an ingredient that is:

1. a gluten-containing grain (e.g., spelt wheat);
2. derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or
3. derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch). Foods labeled “gluten-free” also must not contain more than 20 parts per million (ppm) of gluten.

What products are covered by the final rule?

Food can bear a gluten-free labeling claim if it meets all FDA requirements. The rule applies to all FDA-regulated packaged foods, including dietary supplements.

Where should the gluten-free claim appear on the food label?

Manufacturers may choose where they place a gluten-free claim on their food labels, provided that the claim does not interfere with FDA mandatory labeling information and meets all other applicable statutory and regulatory requirements.

Why is the FDA regulating gluten labeling on food?

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) directed HHS to define and permit the voluntary use of the term “gluten-free” in the labeling of foods.



Does the final rule apply to gluten-free claims made for foods served in restaurants?

The gluten-free final rule applies to packaged foods, which may be sold in some retail and food-service establishments such as some carry-out restaurants.

However, given the public health significance of “gluten-free” labeling, FDA says that restaurants making a gluten-free claim on their menus should be consistent with FDA’s definition.

FDA will continue to work with, educate and monitor industry on the use of the gluten-free claim.

For more information: www.fda.gov/gluten-freelabeling

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